QUERI
Quality Enhancement Research Initiative

QUERI Implementation Guide

Section I Theory and Methods for Integrating Research into Practice

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Section I, Part 1: Models, Frameworks, Strategies, and Tools

A primary lesson learned through all the QUERI work to date in implementing best practices has been the value of basing implementation activities on a structural grounding. It is important to use some form of model or framework to guide implementation research, particularly in planning and constructing strategies and selecting tools for use in an implementation process or intervention to promote evidence-based best practices. Following is a brief overview of models, frameworks, strategies, tools, and specific examples of each.

Why use them?

A very pragmatic reason to use models or frameworks, strategies, and validated tools is that review panels reviewing proposals and grant applications expect to see these used to make the case that the plans being proposed for implementation in the study are feasible. Please see:

- The Program Announcement (PA) for the VA/AHRQ jointly funded solicitation for VA/non-VA projects to Translate Research into Practice (http://grants.nih.gov/grants/guide/pa-files/PA-02-066.html), or
- The Special Solicitation for SDP proposals (http://www.hsrd.research.va.gov/for_researchers/funding/solicitations/SDP-solicitation-July2003.pdf) through VA's HSR&D.

Both of these solicitations require the investigator(s) to show the conceptual underpinnings of the activities they propose, thus researchers planning to work in this area need to have conceptual models and frameworks in order to be funded.

The use of conceptual models and frameworks also aids in ensuring that more than a single contingency is considered, and that multiple aspects of a problem are part of the planning for the proposal. See, in particular, the section on Diagnosis and Targeting (Section I, Part 2 of the QUERI Guide) for a more detailed approach to the use of frameworks, and the decision about how and where to intervene in a process or system.

The use of models and frameworks can put a research project into a much broader context, allowing easier generalization of the knowledge gained by the research endeavor. Widely used, understood models and frameworks also can help promote the association between research activities. In order to enhance the rigor of the research and the quality of the experience for the investigators:

- Search for models that are already described in the literature that fit the concepts being explored; and
- Make appropriate selections of strategies and tools that fit with the models and frameworks.

*****This synopsis was contributed by Anne Sales, PhD, Implementation Research Coordinator for IHD QUERI.

Picking a model or framework

There are no "correct" models in any research endeavor. There are only good, better, and bad fits between a model and a project proposal. Most people choose models that they know and are comfortable with. Psychologists are more likely to choose models that were developed within the discipline of psychology, while sociologists are more likely to choose models developed within or arising out of sociology.

However, many models and frameworks are not specific to any single discipline. In the last several years, with the rise of interdisciplinary teams of researchers within health care and health services, many models and frameworks are explicitly interdisciplinary.

The critical issue in deciding which model or framework to use in a specific proposal or project is the research question being asked or intervention being attempted. Again, a careful reading of the section on Diagnosis and Targeting (Section I, Part 2) will provide a concrete example of the kinds of questions that need to be addressed in deciding where or how to intervene. The model or framework underlying the plans for achieving this intervention should fit the proposed intervention.

The relationship between models and frameworks

For most of us, there is little difference between a model and a framework. Both imply underlying theory about the reasons to expect a specific strategy or intervention to work. In some instances, models are more fully elaborated, and draw more closely on underlying disciplinary theory, while frameworks are sometimes more pragmatic than theoretical, without tight links to well-developed theories in the social, behavioral, or physical sciences. Some frameworks operate primarily by analogy, while others operate by constructing theoretical linkages between one concept and another.

The relationship between models or frameworks and strategies

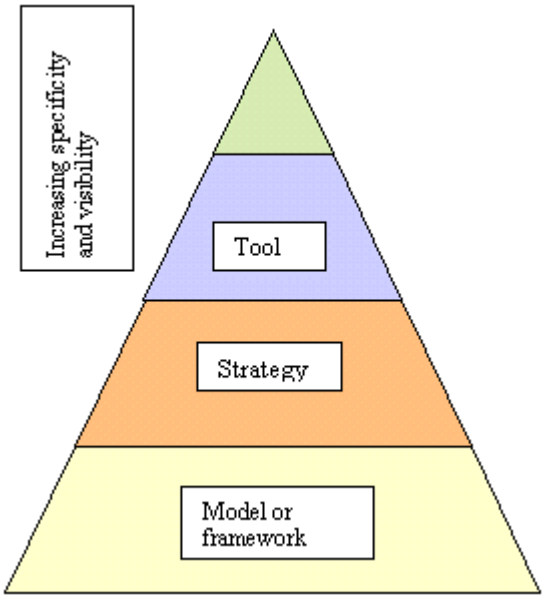
Strategies should flow from the models or frameworks guiding the implementation plan. Planning is always integral to research activities. Research proposals reflect intensive planning, laying out the steps by which a project or program will be executed, or a study conducted. However, because of the nature of implementation, planning takes on additional dimensions in translation research. Such planning goes beyond the traditional, well-controlled activities of a research team and rather must account for the real-time dynamics, players, and context of the practice setting in order to optimize the potential success of the related effort to improve care. Context (see discussion of the PARIHS model) is critical to planning, as are contingency plans to deal with barriers and facilitators.

Strategies are one vehicle for constructing the necessary plans. Examples of strategies that include a great deal of planning include the "Collaboratives," used in the work of the Institute for Healthcare Improvement (http://www.ihi.org/). However, the most effective strategies address root causes of performance gaps or failures in processes or systems. For example, a strategy to rework an entire system of primary care delivery may not be very efficient or effective, if the primary problem underlying a gap between evidence-based best practices and observed system outcomes is due to a knowledge gap on the part of providers or patients. In that case, dealing with the gap in knowledge may be more effective than redesigning an entire system.

Moving from strategy to tools

Selection of tools should be guided by the specific strategies that fit within the framework or model underpinning the implementation effort.

Figure 1 displays one way of visualizing the relationship between models, frameworks, strategies, and tools.



The following sections describe several models, frameworks, strategies, and tools being used by the existing QUERI groups. Researchers initiating implementation research for the first time should note that a selection of these is a time consuming and intensive process, requiring considerable effort on the part of the research team and collaborators in the implementation process. The brief synopses and descriptions you see here provide only an overview of selected approaches.

In addition, research teams should avail themselves of additional resources through Medline searches and other Internet searches. For updates and new models, use a variety of search strategies to locate model, framework, strategy, and tool descriptions. For example, many of the URLs in this section were derived from entering a search term such as "Stages of Change model" into Google (http://www.google.com/). In addition, a number of references are provided. There is

considerable knowledge generation underway in terms of understanding how systems and providers work in our health care systems. The knowledge base is changing and being updated frequently, and some models hold up better than others in terms of the evidence to support the underlying theories.

Selected Models for Use in Implementation Research/Technology Transfer

Effective treatment models for many chronic diseases are not being adopted by providers and provider organizations. This lack of diffusion implies that additional strategies are needed to foster organizational change. We know that passive dissemination of clinical practice guidelines does little to induce change and improve treatment[1] For example, the distribution of treatment guidelines for depression alone does not improve knowledge.[2] Strategies such as detailing can improve knowledge, [3] but do not consistently affect provider behavior. A more comprehensive intervention is necessary to improve care and treatment outcomes—one that takes an active role in partnership with the programs to educate and motivate staff and to tailor an innovation's adoption to best suit programs' structure.

Models for this kind of comprehensive organizational intervention exist in the health services literature. Many are theoretically based in the diffusion of innovation model of Rogers (see for example http://www.ciadvertising.org/studies/ student/98_fall/theory/hornor/paper1.html).[4,5] Rogers' work focuses on the diffusion of innovations and how valuable new approaches (innovations) can spread from innovators to others within a system. The process of adoption on innovation, he describes, is the result of complex interactions between qualities of the innovation (e.g., relative advantage, compatibility, trialability), the nature of the dissemination of knowledge and influence (e.g., opinion leadership, social network structure), and the qualities of the people doing the adopting (e.g., innovativeness) as well as their social structures (e.g., hierarchical, bureaucratic, etc.). In organizations, the adoption process is especially complex, and Rogers lays out several other important interpersonal and contextual factors associated with adoption (e.g., characteristics of individual leadership and the roles of "champions") and organization structures (e.g., formalization and interconnectedness). This theoretical base has influenced the development of quality improvement techniques in industry and healthcare, such as Total Quality Management (TQM) and Continuous Quality Improvement (CQI)6 (examples from the Web include http://www.mapnp.org/library/quality/tqm/tqm.htm).

Not uncommonly, change in health care organizations requires changes in the behavior of health care clinicians. When this is the case the transtheoretical model for behavior change may offer some guidance.[7] This model suggests that change requires (see for example http://hsc.usf.edu/~kmbrown/Stages_of_Change_Overview.htm):

- Movement through motivational stages of change over time (pre-contemplation, contemplation, preparation, action, and maintenance);
- Active use of different processes of change at different stages; and

- Modification of cognition, affect, and behavior.[8]

Dugan and Cohen's interpretation of this model for provider change stressed self-efficacy as an important element in restructuring thought and behavior, as well as the provision of social support and reward for desired behavior change during the "action" and "maintenance" phases. Incorporating the notion of readiness to change at both the individual and organizational levels, Simpson recently offered a program change model for transferring research into practice (see http://www.ibr.tcu.edu/resources/rc-orgfunc.html).[9] This model has provided important conceptual input to many NIDA-funded studies in technology transfer.[10,11,12] Simpson's model involves four action steps:

- **Exposure** – Introduction and training in the new technology;
- **Adoption** – Intention to try a new technology through a program leadership decision and subsequent support;
- **Implementation** – Exploratory use of the technology and
- **Practice** – Routine use of the technology, likely with the help of customization/modification of the technology at the local level.

Crucial to moving from exposure to adoption/implementation are personal motivations of staff and resources provided by the institution (e.g., training, leadership). Moreover, organizational characteristics such as "climate for change" (e.g., staff cohesion, presence of opinion leaders, openness to change) and staff attributes (adaptability, self-efficacy) are central to success in moving from adoption through practice.
A more specific model of health provider behavior change — the PRECEDE model [13, 14] —can be used in the development of the implementation tools in support of the transfer strategy, e.g., feedback of performance data as one example (see for example http://hsc.usf.edu/~kmbrown/PRECEDE_PROCEED_Overview.htm). The PRECEDE acronym stands for "predisposing, reinforcing, and enabling causes in educational diagnosis and evaluation." This model stresses a combination of strategies to influence health provider behavior:

- Predispose providers to be willing to make the desired changes by using strategies such as academic detailing or consultation with an opinion leader or clinical expert;
- Enable providers to change; for example, by providing screening technologies, clinical reminders; and
- Reinforce the implementation of change by providing social or economic reinforcements (see reviews of quality improvement strategies such as those described above.[15,16,17]

Other models have been proposed that focus less on individual provider or patient response to proposed change, and more on the systems of care in which change is being proposed. One example is the Promoting Action on Research Implementation in Health Systems (PARIHS) model (http://www.rcn.org.uk/resources/practicedevelopment/events13.php), initially proposed as a

conceptual framework for understanding the necessary conditions under which evidence-based findings may be accepted in clinical practice.[18-23]
Since it was first developed, this model has been elaborated upon and consists of three parts.[19]
The three parts of the model are:

- Evidence which relates to the strength of the evidence for a desired practice change;[22]
- Context, which describes the environment within which change is promoted (e.g., organizational, political, and cultural);[21] and
- Facilitation, an active ingredient to promoting behavior or organizational change[20] (see http://www.rcn.org.uk/resources/practicedevelopment/practice_processes3_1.php).

Another model focused on changes in the system of care is the Chronic Care Model (CCM), described and developed by the Center for Improving Chronic Illness Care (ICIC); see http://www.improvingchroniccare.org/change/model/components.html. The model explains the relationships between patient outcomes and elements of a healthcare delivery system and as such, guides the development of system changes designed to improve those outcomes. The CCM posits systemic improvements that transform reactive modes of care to those that are proactive via two approaches:

- Promoting provider access to real-time current, centralized patient status information through reminders, and
- Accelerating change by working collaboratively with other provider groups that share similar goals.

Both of these approaches are incorporated, though modified for the VA QUERI setting, into the interventional strategy.

Selected Strategies and Tools for Implementation Interventions

In addition to these models, implementation researchers should consider using predisposing strategies such as:

- On-site opinion leaders,
- Targeted educational sessions and tools for providers/patients and opinion leaders,
- Enabling strategies (i.e., streamlined assessment protocol and clinical reminders to prompt care), and
- Reinforcing strategies (i.e., interactive performance monitoring/feedback and incentives).

The literature on these strategies/tools is largely supportive and is summarized below.
The growing literature on opinion leaders (see for example http://www.managedcaremag.com/archives/0007/0007.opinionleaders.html) in healthcare

behavior change is strong, though not without some mixed results. Several recent studies and reviews indicate the effectiveness of consultation with opinion leaders/clinical experts on improving knowledge and facilitating provider behavior change.[24-30] These studies support findings from non-healthcare settings on the impact of opinion leaders on behavior change in organizations.[31,32]

Academic detailing has been shown to improve knowledge among healthcare providers,[3,24] but this component is not sufficient to bring about the desired change in behavior.[33,34] The provision of targeted clinical reminders *at the time action is necessary* has been shown to improve the performance of the indicated clinical behavior in several studies.[34-36] Further, performance monitoring has been shown to be particularly effective in assisting the implementation of medication use guidelines and to be an important part of many translation/ technology transfer interventions.[37,38]

Collectively, this literature indicates that interventions that have the best success, in terms of improving care delivery and patient outcomes, combine two or more of these strategies (see Figure 1 [39,14,2]). Especially important is working with providers in reviewing the scientific basis for changing a practice behavior[41] and seeking their input in tailoring the intervention to their program[15]

Example 1: **Using the PARIHS Model (Promoting Action on Research Implementation in Health Services) in Ischemic Heart Disease (IHD) QUERI**

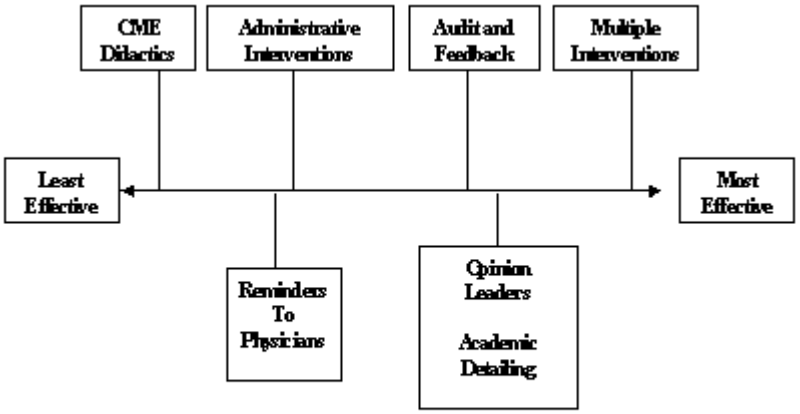
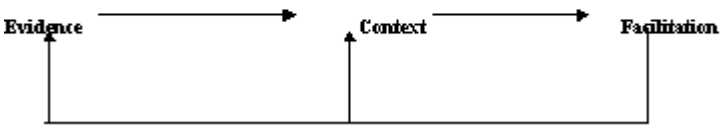


Figure 1: Evidence Map of Quality Improvement/Translation Strategies and Tools (from Weber and Joshi, 2000)

Example 1: **Using the PARIHS Model (Promoting Action on Research Implementation in Health Services) in Ischemic Heart Disease (IHD) QUERI**[5]



Evidence Context Facilitation

IHD QUERI's first efforts at implementing a single evidence-based practice, the control of low density lipoprotein cholesterol (LDL) to reduce risk of recurrent heart attacks, stroke, and death

among patients with known ischemic heart disease (IHD), consisted of working collaboratively with teams of clinicians at several medical centers in one VISN to promote lipid measurement and management. IHD QUERI investigators identified lipid measurement as one part of the process of care that was not being performed well. Despite years of randomized trial evidence, accepted broadly by clinicians and clinical leadership, showing that LDL control is one important method of reducing secondary risk in IHD, more than 30% of patients with known IHD did not have a current LDL measurement on record.[41-43] Without knowledge of current LDL status, clinicians did not have essential information that would lead to control of this risk factor, nor the clinical information to assess adequate treatment.

IHD QUERI recommended several interventions to the medical centers participating in this translation study:

- Initiation of pharmacist-led lipid clinics,
- Use of audit-feedback mechanisms,
- Patient education,
- Nurse-led case management; and
- Point of care reminders.

In addition, at an intervention kick-off meeting attended by teams from six of the eight facilities, information about the use of automatic order sheets for inpatient labs was discussed by a national expert. These interventions were described in detail, with specific costs and benefits of each. Each team selected one or more interventions from this list to use in their facility. Staff from IHD QUERI supported the teams in their chosen intervention with data reports, monthly follow up phone calls, and limited assistance in resolving barriers to intervention in their facility. IHD QUERI reports elsewhere further about the adoption of interventions and the effects seen over a 12-18 month period.[44]

After the intervention period was complete, though some sites continued their interventions, IHD QUERI undertook an assessment of the process and progress of the interventions. One of the realizations was that although the group had collected a considerable number of anecdotes, they had little systematic information that would allow a calculation of the actual "dose" of intervention at each facility. As a result, they followed-up with a retrospective, qualitative study that would allow an understanding of the barriers and facilitators of the intervention at each participating medical center, as well as an estimation of the dose of the intervention. The major findings of this follow-up study are reported elsewhere, but the qualitative study was guided by the PARIHS model.[45]

Specifically, the structured interview protocol was designed using the three components of the PARIHS model: Evidence, Context, and Facilitation. These three meta-themes were then used to group the emerging themes in the content analysis. This approach assured that possible barriers or facilitators were considered, and also provided a framework for structuring the report of the content analysis. Other models or frameworks could have been used, but it was felt that the

flexible form of the PARIHS model worked well for the approach and multiplicity of interventions IHD QUERI attempted to implement.

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Section 1, Part 2: Diagnosis and Intervention Targeting

Overview

Clinical research suggests how we can effectively improve health and quality of life. The first steps in translating research findings into improved clinical practice are *diagnosis* and *intervention targeting*. Diagnosis results in the identification of actionable factors contributing to performance gaps and actionable reasons for failures in implementing innovations. Intervention targeting is the process of choosing a specific focus (e.g., patients, clinicians, information systems) for initiating change.

For example, while we might first observe a performance gap in a VISN level performance measure, further analysis might show that the problem is most closely related to a severe lack of patient knowledge or motivation. Still further analysis may indicate that the most effective practical solution would be the development of an intervention targeted at helping individual providers affect patient activation. Similarly, we might first identify a failure of innovation implementation in individual provider practice, but further analysis might indicate a need to redesign communications between VISN leadership and facility management. [Variation studies tell us the relative level of adherence to best practices across observation units (e.g., VISNs, facilities, clinic, practice teams, providers, patients, etc.)]

Note how in this description we are talking about identifying what we want to try to change, not how we will try to change it. For this reason, diagnosis and intervention targeting can be considered meta-theoretical, or a meta-model of the early stages of an implementation process. By this we mean that the principles of diagnosis and intervention targeting exist independently of a specific theory or implementation model and can, therefore, be used regardless of the theory or model used to design or implement the intervention. While some implementation models such as "Precede-Proceed" actively promote diagnosis and targeting principles, they can be adapted to other models as well.

Diagnosis and intervention targeting always precede change efforts, but sometimes it is not readily apparent. For example, many times diagnosis and intervention targeting are implicit: a performance gap is observed and a decision is made to focus change efforts at persons or systems based on expert judgment or historical precedent. The problem with implicit methods is they are not transparent -- others who do not share our expertise or culture may not understand why we have made the choices we have. This chapter will focus on explicit, formal, diagnosis, and intervention targeting.

Remember, diagnosis and intervention targeting are not all-or-none ventures. You can do just enough to determine that you may not need more.

Interdisciplinary Nature of Implementation

All aspects of implementation research and implementation practice are inherently interdisciplinary, but perhaps none more so than formal processes of diagnosis and intervention targeting. An implementation researcher, or practice specialist, does not need to be a content expert in each relevant discipline. However, the implementation researcher must be aware of the breadth of perspectives and resources available, and when and how to integrate each into his or her research and practice.

This section presents a variety of tools and explains how they may affect implementation research and practice, and imparts enough basic terminology to facilitate communication with relevant consultants. The topics of intervention mapping and intervention design are not part of this chapter. These topics will be featured in a future version of this Guide. The interested reader can review: "Intervention Mapping, Designing Theory- and Evidence-Based Health Promotion Programs" by Bartholomew, Parcel, Kok and Gottlieb (2000, McGraw-Hill). In addition to a meta-theoretical description of the intervention design process, Bartholomew et al give detailed examples of theory-driven intervention design using a variety of health promotion theories. A further resource is an article by van Bokhoven, Kok, and van der Weidjen titled "Designating a quality improvement intervention: a systematic approach, " in *Quality and Safety in Health Care*, 2003;12/3:215-220.

Section Plan

Part I: A Case Study in Diagnosis and Intervention Targeting

Part II: An Introduction to Systems Thinking

Part III: What Does Systems Thinking Contribute to Diagnosis and Intervention Targeting

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A Case Study in Diagnosis and Intervention Targeting

This section illustrates the process of diagnosis and intervention targeting through the use of a case study from Colorectal Cancer QUERI. The working definition of diagnosis and several distinctions related to diagnosis and needs assessment must first be made. In the discussion here, *diagnosis* refers to the specification of actionable contributing factors to performance gaps and/or failures of innovation implementation.

While diagnosis is similar to the public health/psychology construct of "needs assessment," it is more specific. Needs assessment encompasses both the measurement of performance gaps and the specification of all contributing factors, while diagnosis is limited to making a specific, explicit connection between an observed performance gap and root causes or conditions that may be amenable to change (actionable). Needs assessments are primarily *descriptive*, while diagnosis is intended to be *prescriptive*. While needs assessment data are often one of the outcomes of "variation studies," diagnosis goes a step further toward implementation.

Variation studies are *descriptive* of performance gaps, while diagnosis produces a *prescriptive* identification of what needs to change to resolve the gap.

Diagnosis Steps

There are three key steps required for diagnosis: 1) Developing a task model (i.e., generally outlining all the tasks required); 2) Outlining the performance model (i.e., finding out how the tasks are performed at a particular setting); and 3) Determining how well each task accomplishes its objective.

Step One

Recent evidence indicates that fewer than one-third of patients with positive fecal occult blood test (FOBT) findings receive the necessary complete diagnostic evaluation colonoscopy (CDEC). The development of a generic process model or roadmap for the task in question, often called a "task model" – is illustrated by the following questions regarding evidence of a performance gap.

Variation study questions:

- What is the level of CDEC at VHA facilities nation-wide?
- What are the organizational, staffing, and demand characteristics of facilities with high CDEC vs. low CDEC?
- What other factors correlate with CDEC rates across facilities?

Non-diagnostic needs assessment questions:

- Which facilities are most in need of improvement assistance?
- What, if any, are fundamental resource shortfalls at each site?

Diagnostic questions at each facility:

- How are providers informed of positive FOBT results?
    - How effective is this process?
- How do patients with positive FOBT results get referred for CDEC?
    - How effective is this process?
- How are patients' scheduled for CDEC?
    - How effective is this process?
- How are patients instructed in the necessary at-home prep for CDEC?
    - How effective is this process?
- Are patients given any other prep support?
    - How effective is this process?
- Are patients given transportation assistance to get to and from the CDEC appointment, or assessed for transportation need?
    - How effective is this process?
- How is CDEC appointment adherence managed at this facility?
    - How effective is this process?

The explicit task model for receiving a CDEC after a positive FOBT includes the following.

- Provider must be informed of positive FOBT findings.
- Provider must recommend and order CDEC.
- Patient needs to be scheduled for CDEC.
- Patients must be provided with the materials and instructions for the required at-home preparation (purging) for the CDEC.
- Patients need to adhere to the required prep protocol.
- Due to sedation, patients must have an escort to and from the clinic on the day of the procedure.
- Patients must show up for the CDEC appointment.

Step Two

The second step in diagnosis is specification of how that task model is implemented in each facility to produce the observed performance is the "performance model." The performance model is derived from the answers to each of the questions given above. Each site may have a unique performance model, or several classes of performance models may be identified, but all performance models can be mapped to the task model.

Step Three

The third step in diagnosis is determining the effectiveness of each of the individual tasks in the performance model by answering the question: "How effective is this process at each step?" Outlining the task model, specifying the performance model, and assessing the effectiveness at each step in the performance model offers the information required to determine which steps in the performance model need to be improved at each facility.

A Tale of Two CDEC's

Hypothetical data for two imaginary health care facilities are presented in the table below (the data are taken from actual findings across multiple facilities). There are performance gaps at both facilities. At Facility A, 30% of persons with a positive FOBT receive a CDEC, and at Facility B, 34% of persons with a positive FOBT receive a CDEC. Performance models (how each facility accomplishes each step in the task model) for each facility were determined using the questions above. Effectiveness at each step is included if known.

Performance Model, Facility A	**Performance Model, Facility B**
• Provider looks up CPRS lab result (rate unknown). • Provider issues CPRS consult request to GI endoscopy (50% of FOBT positive cases). • GI clinic schedules patients (100% of orders are scheduled for either flexible sigmoidoscopy or CDEC). • Nurse educator instructs all patients in home prep (100% of those scheduled receive this instruction). • No other prep support is given (90% of patients who show up in the clinic are properly prepped). • Patients are assessed for transportation support at the time of scheduling and are diverted to follow-up using flexible sigmoidoscopy or barium enema if no escort is available and the patient is considered low risk. High risk, unescorted patients have CDEC done as inpatients. • An appointment reminder phone call is made three days before the CDEC appointment (67% of patients show up for the appointment). • 50% referral rate * 67% appointment adherence * 90% adequate prep = 30% successful CDEC	• Lab result emailed to all providers (100% of FOBT positive, unknown whether all are noted by providers). • Provider issues CPRS order to GI endoscopy (75% of FOBT positive cases). • GI clinic schedules patients (100% of orders are scheduled for either flexible sigmoidoscopy or CDEC). • No pre-CDEC education. • No other prep support is given (70% of patients who show up in the clinic are properly prepped). • No transportation support or screening is offered. • No appointment reminders are used (65% of patients show up for the appointment). • 75% referral rate * 65% appointment adherence * 70% adequate prep = 34% successful CDEC

Preliminary Conclusions

Although the performance gaps are similar, the contributions of subtasks in the performance model are different between Facility A and Facility B. Facility A needs to improve its referral system more than Facility B, while Facility B needs to improve patient completion of prep. Both facilities could improve appointment adherence. Facility A has already implemented several strategies in these areas that Facility B has not yet deployed, and Facility B has implemented a change in how providers are notified of positive results.

Before Making the Diagnosis: Is it really sub-standard performance?

Before making final conclusions, let's investigate further. Pick up where the diagnosis left off, then diagnose a little more. The referral rate for Facility B was 75%. Is this adequate? Additional probing identified known causes of lower GI bleeding in half of the non-referred cases, a recent colonoscopy in another 10% of cases, and significant comorbidities that ruled out colonoscopy in another 15% of cases. So providers were appropriately excluding approximately 20% of patients with positive FOBTs from the referrals. The suspected failure rate for referrals is probably closer to 5%, and providers may be able to justify these exclusions as well. While we may need to come back to this in the future, changing referral patterns at Facility B is not recommended. The referral rate at Facility A was 50%. Only about 10% of the non-referral cases could be explained by adequate referral exclusion reasons. Therefore, referral rate improvement at Facility A should be targeted.

Intervention Targeting: How do I do this? (A tale of two CDECs continues.)

Intervention targeting is the process of choosing a specific focus for initiating change. An intervention target is specified in the following way – it includes both the target people/system involved (patients, clinicians, clinic system) and the subtask. For example, an intervention might target patients' contributions to appointment adherence, providers' contributions to making patients aware of the required prep for the exam, clinic systems' contributions to setting up appointments, or providers' contribution to ordering colonoscopy exams.

Making the business case for change: Look for the 90% solution

The business case is a statement of what resources will need to be invested and an estimate of potential gains in performance. Necessary resources include:

- Facilitation effort,
- Provider effort,
- Patient effort,
- Administrative effort, and
- Material resources ($).

Initially, consider targeting interventions at the observational unit and process model node that maximizes potential return on investment, then reassess and decide if more work is needed. Often the most gain can be obtained with minimal investment. These are called "90%" or "90/10" solutions.

Low hanging fruit: What is the easiest course of action?

The rate at which providers in Facility A look up lab results is unknown. It could be measured, and if we find out that the rate is low, an intervention to change the providers' behavior could be undertaken. But emailing results to providers is associated with a higher referral rate in Facility B. Targeting a system change that supports providers by lessening the effort required to do their jobs is an example of low-hanging fruit.

Sometimes you don't cross a chasm in two steps.

In Facility B, the diagnostic analysis shows a diffuse set of gaps across the GI prep and appointment adherence part of the process. No single intervention target stands out as a major contributor to the performance gap. If both prep adherence and appointment adherence in GI at Facility B need to be changed, then this may be more readily accomplished as a single system redesign effort, rather than successive piecemeal interventions.

Staging sequential interventions -- Sometimes you DO cross a chasm in two steps (but do so carefully).

Think about what effect the proposed intervention will have on downstream nodes in the task model. You may need to target your first intervention at a point further along in the task model to prepare for increased demand that may result from the main intervention. For example, Facility A's low referral rate and the availability of a low-cost intervention make the referral system a reasonable intervention target. But what effect will this have on nodes further along in the process model? Facility A has a 67% appointment adherence rate and a 90% prep adherence rate, and increased referrals will put more demand on the prep education and appointment reminder systems. Will the current rates hold up or decline? What kind of intervention targeted at the prep education and appointment reminder systems will maximize their ability to deal with demands generated by increased referrals?

How-to Summary:

Diagnosis:

- Construct a generic task model.
- Construct a performance model that shows how the task model is accomplished in each setting.
- Evaluate the level of performance at each node in the task model in each setting.

Intervention targeting:

- Look for 90/10 solutions.
- Harvest low-hanging fruit and, when possible, take the course of least resistance.
- Look for opportunities to combine multiple interventions into a cohesive system re-design, BUT…..

- Make sure the observed deficits don't have a rational explanation, and
- Make sure the fix for one problem doesn't cause another problem downstream – fix the downstream problems first.

The case study, as illustrated, shows the process after completion, but how do you generate a diagnosis and intervention-targeting plan from scratch? Some tools discussed later in this section were implicitly used in the above example (i.e., use of existing data, means-ends analysis, decision trees, etc.). However, the fundamental concept running through this example is the necessity of systems-thinking. The task model represents the generic system. The performance model represents a setting-specific system. Evaluating effectiveness at each process step is a systems approach. Making the business case, finding the low-hanging fruit, and knowing how to sequence sequential interventions are all systems concepts.

An Introduction to Systems-Thinking

Systems-thinking is fundamentally different from traditional analysis. Traditional analysis focuses on separating individual elements of what is being studied to identify increasingly finer level explanations for phenomena, or "lower level causes." This is often referred to as "reductionist-thinking." An example of reductionist-thinking is the traditional view that psychological phenomena can be understood by understanding the underlying biology, the biology by chemistry, and the chemistry by physics. Instead, systems-thinking focuses on how elements interact and their mutual dependencies (intentional or coincidental), and how these interactions and dependencies produce observable processes and behaviors. While traditional analysis is often a part of a systems-thinking approach, the systems-thinker will typically use traditional analysis to identify a system-level where the phenomena of interest is "emergent" and not look for lower level causes than this.

Why Do We Need to Become Systems-Thinkers?

Systems-thinking usually produces radically different conclusions from reductionist thinking. In particular, systems solutions are more often directly actionable, especially in dynamic and complex settings, and environments with a great deal of feedback from other sources, internal or external – like large healthcare systems.

Systems-thinking allows people to make their understanding of social systems explicit and improve them in the same way that people can use engineering principles to make explicit and improve their understanding of mechanical systems.

What is a "System?"

A system is an entity that maintains its existence through the mutual interaction of its parts. Systems exhibit emergent properties; these are characteristics that emerge from the interactions between the parts of the system and cannot be found in any of its parts alone. Being aware of how multiple systems and sub-systems may interact will help with relevant aspects of the

implementation task. Systems can be described in terms of their goals, inputs, outputs, processes, and component parts or sub-systems.

The colorectal cancer screening and follow-up system will be used to illustrate. The colorectal cancer screening and follow-up system maintains its existence through the mutual interaction of primary care, laboratory, and GI specialty clinics, as well as the more diffuse and external systems of patient adherence to appointments, and interactions with numerous other components of the medical center. Colorectal cancer screening and follow-up includes the referral/scheduling process. Productive communication among lab, GI, and primary care does not wholly reside in any one of these sub-systems, but is an emergent property of their interaction. Any agent (person or organizational entity) may simultaneously be a component in multiple systems. A primary care provider who is part of the colorectal cancer screening system will also play a role in other clinical sub-systems that originate in primary care. The provider may also be a part of administrative systems.

The goal of the colorectal cancer screening and follow-up system is to improve patient survival and quality of life through early detection and prompt treatment of colorectal cancers and pre-cancerous polyps. The inputs into the system are patient health status, patient and provider knowledge and attitudes, clinic resources, etc. Processes within the system include: patient health care seeking, patient-provider shared decision making, clinical informatics, communication and specialty referral, and patient education. The outputs of the system are screening rate, CDEC rate, treatment rates, mortality and quality of life effects.

Formal and Informal Systems

It is important to identify and consider both formal and informal systems when translating research into practice in clinical settings. Formal systems are objective in that they exist apart from any external observer. They are systems that are prescribed, mandated, or formally incorporated and/or organized. They include, but are not limited to organizational entities (divisions, departments, etc.), professional societies, organized advocacy groups, and so forth. The nominal goals, inputs, outputs, processes, and component parts or sub-systems of formal systems are typically documented and may evolve over time to differ significantly from the documented components. While documented nominal components are a good introduction to formal systems, effective implementation work requires understanding the functional components, that is, how a particular system actually operates.

In contrast to formal systems, informal systems are subjective; they only "exist" as observer constructs. They are descriptions of observed goals, processes, interactions among entities and behaviors. Some examples of formal and informal systems may serve to illustrate. The VHA is made up of multiple embedded, overlapping, and interacting systems, both formal and informal.

Examples of formal care systems that exist within the VHA include VISNs (Veterans Integrated Service Networks), the regional organizations for VHA, services lines, facilities (i.e., medical center and affiliated community-based centers), stations (specific community-based outpatient clinics or medical centers), care units within a facility (e.g., clinics such as primary care or gastroenterology), and support units (chaplaincy, patient education, pharmacy, etc.).

Examples of *informal care systems* may be groups of providers who interact regularly, but are not part of a formal organizational network or patient social support during regular transportation to clinics or in waiting rooms. The goals, processes and behaviors represented by both formal and informal systems have profound effects on health care and outcomes. Both are vital mediators of change, and both formal and informal systems should be considered in diagnosis and in intervention targeting.

Examples of formal systems

Formal management systems:

- Veterans Health Administration (VHA)
- Patient Care Services (PCS)
- Office of Research and Development (ORD)
- Operations and Management
- Office of Information
- Formal resource systems **(link to this part of the guide)**
- VA Information Resource Center (VIReC)
- Health Economics Resource Center (HERC)
- Management Decision and Research Center (MDRC)
- Measurement Excellence and Training Resource Information Center (METRIC)

See http://vhacoweb1.cio.med.va.gov/skm/images/Org-Chart-Overview.pdf for a complete organizational chart for the Veterans Health Administration; see also Section III, Part 1.
Formal provider systems:

- Professional groups organized by discipline (i.e. dentistry, nursing, physicians, psychology, osteopathy, etc.)
- Professional groups organized by practice specialization (i.e. primary care, mental health, surgical, etc.)
- Clinic care teams or firms
- Gastroenterology department

Formal patient systems:

- Biological and legal family units
- Patient advocacy groups

Examples of informal systems and system resources

Informal care systems:

- Patient social support
- Friends
- Spiritual community
- Neighbors
- Under some circumstances, patient self-care can be viewed as a system

Informal staff networks

- Patient-focused ad hoc teams; for example, the nurse refers the patient to a specific patient care rep, or the physician says "you ought to talk to nurse 'x' in extended care." These represent knowledge moves across local experts.

Off the record records

- To keep recorded wait times down some clinics keep pencil and paper waiting lists and enter appointments into the computer as slots open up.

Knowledge as currency

- Sometimes certain knowledge gives someone leverage in the organization, and it becomes against his or her best interest to share it freely.
- Sometimes merely acting like one has knowledge is equally valuable. This leads to secretive, defensive behavior to preserve the illusion of power.

Management knowledge moves and local experts

- Consultation and responsibility shifting in informal staff teams across formal departments.
- When knowledge is a currency, competing informal management teams will partition real and imagined knowledge into "territories."

Informal provider systems

- Provider-focused systems to improve job satisfaction and/or performance.

- Social support on and off the job.
- Dysfunctional cases may include implicit or explicit manipulation of others.

What Does Systems-Thinking Contribute to Diagnosis and Intervention Targeting

Systems-thinking helps us with problem diagnosis and intervention targeting by allowing us to recognize when a system is not functioning as designed.

How to diagnosis: We can map out a task model and/or performance model. Analysis of the effectiveness of the system at each node tells us what needs to be fixed. We may find that a specific observation unit (i.e., clinic) has skipped a step in the process.

Intervention targeting: The results of diagnosis point to specific nodes that need to be addressed and may identify 90/10 solutions or point to the need for system redesign. Understanding inputs, outputs, and goals of embedded sub-systems will help:

- Identify low-hanging fruit,
- Point to mutual dependencies that may require sequencing of interventions, and
- Identify missing sub-systems or stakeholder groups who need to be involved.

Systems-thinking allows us to identify when a system can be repaired, and when it needs to be redesigned.

How to diagnosis: If there are serious deficits at each step in the performance model, redesigning the system may be necessary. Repair may not be feasible, especially if the deficits are restricted to a specific sub-system.

Intervention targeting: What appear to be isolated large deficits will have so many downstream consequences and sub-system interdependencies to work through that system redesign is called for in these cases too.

Systems-thinking allows us to understand how the normal functioning of an intact system may result in performance gaps or innovation lags.

How to diagnosis: If we map out the system's functional goals, inputs, outputs, processes, and component parts or sub-systems, we can often find logical errors, barriers, or resource deficiencies.

Intervention targeting: We can perform virtual "tests" on potential interventions using our system models to determine how much improvement we might reap from each potential intervention.

Systems-thinking allows us to understand how normal functioning of multiple systems can produce performance gaps through conflict.

How to diagnosis: If we map out the systems' functional goals, inputs, outputs, processes, and component parts or sub-systems, we can often find conflicts between dependent inputs and outputs, conflicting goals, or attempts to access the same limited resources.

Intervention targeting: Using our systems models, we can check to see if proposed interventions to resolve one set of conflicts create new conflicts.

Conducting Diagnosis and Intervention Targeting

How Do You Conduct Diagnosis and Intervention Targeting? How Do You Map Out Systems?

Identify the problem

There is usually some trigger that leads to the effort to conduct diagnosis and subsequent intervention targeting. Implementation efforts may be triggered by either observations of substandard or sub-optimal performance, or by observations that proven innovations are not being applied in the field. Diagnosis and intervention targeting efforts are often influenced by the impetus for the implementation effort. Some examples:

The observed performance gap:

- The performance gap is a deficiency in one of the outputs of the main system of interest. It may even be a goal state. In the CDEC example, fewer than one-third of patients with positive fecal occult blood test (FOBT) findings received necessary complete diagnostic evaluation colonoscopy (CDEC).

Identifying an innovation lag or problem:

- A new device, drug, policy, or process is deployed to a setting and is not being used, is being used incorrectly, or is being used and is having undesirable effects.

Specify the task model

Use means-ends analysis to develop a basic sequential task model or sub-goal structure. For example,

- We want patients to complete CDEC after positive FOBT findings.
    - What conditions must they satisfy immediately prior to the CDEC?
        - They must be adequately prepped and show up for the appointment.
- What must they do to be adequately prepped?

- They must do the at-home prep protocol,
- Have the materials for the prep, and
- Understand how to do the prep.

Specify the performance model

How is each node of the task model accomplished or represented in each setting? Representation of concepts such as nodes in a task model is called *instantiation*.

- Describe how each step in the task model is accomplished at each setting.
- Identify the appropriate formal systems that provide input or processes to the system.
- Identify and document informal systems.
- List the inputs and processes that link the sub-goals of the task model.

Construct a decision- tree to model choice processes that connect each sub-goal to the next.

Decision-trees are frameworks for making explicit when choices must be made and differentiating the frequency with which different paths between sub-goals may be pursued. For example, CDEC at Facility A: Patients are assessed for transportation support at the time of scheduling and diverted to flexible sigmoidoscopy or barium enema if no escort is available and the patient is considered low-risk. High-risk, unescorted patients have CDEC done as inpatients. This represents a decision point at which three different things may happen depending on the circumstances: 1) If transportation available, proceed with outpatient CDEC; 2) If no transportation and the patient is deemed low-risk, divert to outpatient flexible sigmoidoscopy or barium enema; or 3) If no escort available but the patient is at higher risk, schedule an inpatient CDEC.

Sometimes decision-tree models incorporate the cost or value associated with each choice as an aid in making new decision rules. For an example, go to:

http://www.mindtools.com/dectree.html

Measure outputs at each step of the performance model

- Identify the desired output at each step
- Identify sources of data for determining output at that step
- Collect data
- Include outputs in description of the performance model to assist in diagnosis

Don't overlook the possibility of using existing datasets. VA datasets have a wealth of data that may already be sufficient to estimate performance levels at each process node, and they include:

- Veterans' Integrated Health Systems Technology and Architecture (VistA),
- National Patient Care Database (NPCD),
- Decision Support System (DSS), and

- External Peer Review Program (EPRP).

In the CDEC example, we obtained data on:

- Number of FOBTs processed (NPCD),
- Number of positive FOBTs (VistA),
- Number of referrals for CDEC (VistA),
- Number of completed CDECs (NPCD),
- Endoscopic prep adherence rate (VistA),
- Endoscopic appointment adherence rate (DSS),
- Clinic wait times (DSS),
- Clinic staffing levels (DSS),
- Mapping of providers to clinics (NPCD), and
- Number of other endoscopic procedures (NPCD).

The benefits of using existing data include:

- It's cheap,
- It's available, although getting data may require specialized knowledge of the databases and data extraction techniques, and
- Data collection will not affect clinic operations.

However, if there are no existing data sources that meet the needs, then primary data collection will be necessary to complete this part of the diagnosis. However, perhaps not all steps require the output measures. Think about potential sources of data broadly. Having some information through discussions with clinic staff may offer an estimate that is enough to serve your purposes for determining the extent of the problem. For example, in the tale of two CDECs there is no data on the proportion of persons for whom having an escort is an issue – so we don't know how much of a problem this presents. Perhaps asking patients and tracking this for a short period of time would be sufficient for purposes of the diagnosis, or starting with a discussion with those persons who do the scheduling. They may already be able to estimate whether it is 5% of persons who have a problem or 30%.

Identify actionable factors for intervention

In the tale of two CDECs, the overall performance gaps were found to be similar, but there were differences in the contributions of subtasks – so that the factors identified for intervention were as follows:

- Facility A needs to improve the referral system, and appointment adherence.
- Facility B needs to improve completion of prep, and appointment adherence.

Intervention targeting

An intervention target is specified in the following way – it includes both the target people/system involved (patients, clinicians, clinic system) and the subtask. Start with diagnosis of a gap in performance and other possible gaps. However, some performance gaps are not readily amenable to "repair" approaches, and may require more extensive work – sometimes full-scale system redesign. The following is a brief discussion of instances in which more extensive work is required.

Examples of Diagnosing and Targeting Interventions

Example 1: *Diagnosing a performance gap: Refer to the CDEC example.*

Example 2: *Diagnosing an innovation lag: A new device, drug, policy, or process is deployed to a setting and is not being used, is being used incorrectly, or is being used and having undesirable effects.*

- Map out the task model.
- Map out the pre-innovation performance model of the innovation site (M1).
- Map out the ideal performance model of the innovation (M2).
- Map out the post-innovation performance model of the innovation site. (M3).
    - What are the differences between models M2 and M3?
    - What needed to happen to convert performance model M1 to performance model M2?
    - Can this be done in this setting, or will the change set up irresolvable conflicts among sub-systems?

Implementation efforts involve both concrete, objective systems assessment and change, as well as a need for awareness of the psychosocial or political climate at hand.

Example 3: *Targeting an intervention around a formal system property*

Sometimes, formal system properties will put limits on our ability to produce performance improvement. For example, staffing levels or equipment or other material resources may be fixed. These limiting conditions need to be estimated at the outset. All stakeholders must acknowledge their existence and the limits they impose on expected changes. For example, even if all CDEC performance model nodes are performing at a high level (e.g., perfect referral rates, perfect prep rates, perfect appointment adherence, etc), staffing levels will still impose a fundamental restriction on the number of CDECs that can be performed. The demand for CDEC and the staffing level also will restrict the timeliness of CDECs. If the health system needs to see performance levels that exceed these limitations, they will need to change the system resources, processes, or goals.

Examples of formal system changes:

- Hire more VA GI specialists.
- Contract CDEC to non-VA GI specialists.

- Train non-GI physician endoscopists or non-physician endoscopists. For example:
  - Do existing staff perform other endoscopic procedures that might be diverted to other personnel to free up endoscopic capacity?
  - Would a phased-change, risk-adjusted endoscopy model, in which only the highest-risk cases receive immediate CDEC, while low-risk cases receive other diagnostic tests be acceptable?

Example 4: *Targeting an intervention around a psychosocial/political problem*
Pre-existing relationships among persons in diverse organizational units must be respected while we work toward buy-in for change. For example, in many VA medical centers, several autonomous provider groups offer colonoscopy services. Independent CRC screening programs may be available through practitioners in:

- GI,
- GI endoscopy,
- Colorectal Surgery,
- General Surgery, or
- Proctology.

While it may look good "on paper" to split the facility-wide demand for CDEC across all providers, regardless of group membership, there are probably strong (informal) system barriers to this in place. Part of negotiating how these groups may best work together is to acknowledge that each provider group has a unique history, goals, and processes.

Web Resources

A wide variety of disciplines contribute to the methodology of systems and task analysis, and problem diagnosis. Here are links to some detailed resources representing the diversity of the field. Inclusion of a site link does not constitute an endorsement of any tool for any specific purpose. *No endorsement of any links followed from these sites is intended*.

Web resources for Systems Thinking

- http://www.thinking.net/index.html
- http://www.systems-thinking.de

Engineering/Design/Quality Management Methods
Systems analysis: Ways to develop systems models, implications of systems thinking.

- http://pespmc1.vub.ac.be/ASC/SYSTEM_ANALY.html

Theory of Constraints/Throughput Analysis: Systems models that are focused on converting "inputs" to "outputs."

- http://www.sytsma.com/cism700/toc.html
- http://www.thedecaloque.com/
- http://www.ciras.iastate.edu/toc/

Task Theories/Task Analysis: A Variety of Concrete Methods for Deriving Task and Performance Models.

- http://ericacve.org/docs/taskanal.htm
- http://www.cdc.gov/niosh/mining/hfg/taskanalysis.html
- http://www.psych.upenn.edu/~saul/a+p.xx.pdf

Risk Analysis and Systems Analysis methods based on the concept of risk. Although usually applied in a safety context, "demand" is a type of risk. How might use risk analyses be used to represent demand for services? How does this view differ from through-put analysis?

- http://www.sra.org/
- http://www.hcra.harvard.edu/

Root Cause Analysis Methods of attributing causation to sequential processes within systems. Root causes are best candidates for interventions.

- http://www.patientsafety.gov/tools.html
- http://www.systems-thinking.org/rca/rootca.htm

Cognitive/Behavioral Science Methods
Performance Theories/Behavior Analysis: Behavior analysis and behavioral task analysis focus on motivational factors (stimuli, reinforcement, etc) in system processes.

- http://www-ee.uta.edu/hpi/PAGES/gspt_main.html
- http://www.coedu.usf.edu/behavior/bares.htm
- http://www.saem.org/download/01militello.pdf

Knowledge Engineering/Knowledge Acquisition: Knowledge engineering and acquisition methods seek to understand the basis of decision-making within system processes. This might include motivational and factual components.

- http://pages.cpsc.ucalgary.ca/~kremer/courses/CG/CGlecture_notes.html
- http://carlisle-www.army.mil/usacsl/divisions/std/branches/keg/keg.htm

- http://www.cs.newcastle.edu.au/~vlad/kddm.html

Means-Ends Analysis: Means-ends analysis may be used as a tool to map out system sub-goals, or as a weak problem solving method.
Social Cognitive Theory seeks to understand system processes as part of a social context. This is useful for mapping out goals and relationships among persons who are active participants in multiple systems; also useful for understanding conflicting goals.

- http://hsc.usf.edu/~kmbrown/Social_Cognitive_Theory_Overview.htm

Management Science/Operations Research Methods: Cost Effectiveness Analysis is a diagnostic measurement approach that considers resource utilization. Effectiveness may include estimates of the "utility" or value of outcomes.

- http://www.acponline.org/journals/ecp/sepoct00/primer.htm
- http://www.ahcpr.gov/research/costeff.pdf

Technical Efficiency Analysis: A diagnostic measurement approach that considers resource utilization, but allows each observation point to optimize different criteria. For example, some clinics may produce shorter wait times given the number of patients they see, while other clinics might complete more procedures annually given their patients' multiple comorbidities. This helps identify different strategies of approximating "best practice," when there are multiple system inputs and outputs, as well as scaling relative efficiency of observational units.

- http://www.deazone.com/

Part 1 Section 3: Methods Used in Translating Research into Practice

In describing methods that are appropriate to use across the pipeline of activities involved in moving research evidence into practice, it is helpful to understand the larger context of the QUERI program and its current (as of 2004) portfolio of activities. QUERI targets nine conditions/diseases that are prevalent among veterans, including: chronic heart failure (CHF), colorectal cancer (CRC), diabetes mellitus (DM), HIV/AIDS, ischemic heart disease (IHD), mental health (MH), spinal cord injury (SCI), stroke (STR), and substance use disorders (SUD). Additional conditions may be added periodically. This section of the Guide includes:

- An overview of the QUERI approach,
- The QUERI process with examples of methods,
- Typology of QUERI implementation project designs, and
- Resources detailing these and related methods.

Most health services researchers have received a significant amount of training in study design, and are generally prepared to use the texts and references cited throughout and at the end of this section. Rather than attempt to replicate or reproduce the work of literally hundreds of texts and articles, we refer you to them. If these are not easily understood, we recommend working closely with a seasoned methodologist or researcher with a background in implementation of quasi-experimental and other non-randomized controlled trial designs or in program evaluation.

The Big Picture: Efficacy to Effectiveness Trials

Recently, Glasgow and others[1] reviewed the distinctions between efficacy and effectiveness studies within the larger context of the Greenwald and Cullen model of sequential phases of intervention research.[2] According to this scheme, benefits of interventions are first tested in small-scale, tightly controlled *efficacy* trials. Once benefits are demonstrated under those conditions, improvements in outcomes are then tested in larger, real world settings via *effectiveness* trials. QUERI's portfolio is largely comprised of effectiveness-style research. However, according to the Greenwald-Cullen model, effectiveness studies are necessarily followed by large-scale demonstrations, or what they refer to as *dissemination* projects.

The QUERI Process and Methods

It would be difficult to describe appropriate methods used in QUERI-related research and program evaluation outside of the context of the Six-Step Process that has guided QUERI activities since its inception. The steps in the table below have been slightly modified from their original form in order to better reflect the current understanding of how classic research methods complement the

process of implementation. The table also includes methods that would be appropriate in addressing each step, as well as examples that have been or could be used by QUERI groups.

The original Six Steps have been supplemented by two foundation steps – Step M and Step C that are considered to be outside of the core QUERI process, although they support the process. Step M Projects may be conducted through QUERI if viewed as critical for subsequent steps. Step C projects are generally funded through the Clinical Science and Health Services Research and Development programs.

Descriptions	Typical Methods	QUERI Examples
Step M: Develop Measures, Methods, and Data Resources		
Develop &/or evaluate… **M1**: …patient registries, cohort databases, data warehouses **M2**: …casefinding or screening tools **M3**: …structure, process, or outcome measures **M4**: …organizational structure/system, clinical practice, utilization or outcome databases	-Develop databases -Develop measurement tools	-Development of HIV patient research database -Design of HIV casefinding algorithm -Design of provider perceptions/attitudes survey instrument
Step C: Develop Clinical Evidence		
Develop evidence-based… **C1**: …clinical interventions, recommendations **C2**: …health services interventions	-Systematic research reviews -Panels of experts -Delphi Method for consensus building	-Construction of guidelines for treatment of depression in HIV patients on antiretroviral medication regimens
Step 1: Select Diseases/Conditions/Patient Populations		
Identify… **1A**: …(and prioritize via a	-Epidemiological studies (e.g., incidence and	-QUERI group conditions identified as priorities for VA

formal ranking procedure) high-risk, high-burden clinical conditions **1B**: …high priority clinical practices, co-morbidities, and outcomes within each condition	prevalence) -Measurement of disease burden (e.g., cost, health status) -Observational studies of behaviors/practices	based on epidemiologic evidence, incidence, and prevalence within VA healthcare system - Identification of lipid and blood pressure manage-ment as important clinical targets for diabetic care - Measurement of recommended antiretroviral drug use for VA patients with HIV/AIDS
Step 2: Identify Evidence-Based Guidelines/Recommendations		
Identify evidence-based… **2A**: …clinical practice guidelines **2B**: …clinical recommendations	-Large scale clinical trials -Formal systematic research reviews or syntheses of best practices -Empirical validation of best practices	-Ongoing meta-analyses of antiretroviral drug trials -Development of VA diabetes evidence-based guidelines - Guideline modifications made for eye care in diabetics
Step 3: Measure and Diagnose Quality/Performance Gaps		
3A: Measure existing practice patterns and outcomes across VHA and identify variations from evidence-based practices (quality, outcome, performance gaps)	-Measurement of practice variation -Modeling determinants of clinical practices	-Baseline measurement of HIV screening prevalence -Cost analysis of staffing require-ments for HIV/Hep C

performance gaps) **3B**: Determine current practices, as well as barriers and facilitators to improving practice **3C**: Diagnose quality gaps and identify barriers and facilitators to improvement	-Observational, cross-sectional, and longitudinal studies -Focus groups (e.g., of providers)	care delivery model -Cost effective-ness analysis of an HIV screening program -Modeling facilitators and barriers to improving practice for HTN treatment and control -Measurement of delays in laser therapy for diabetic retin-opathy and reasons for delays -Survey of variations in HIV provider attitudes and facility policies for HIV care
Step 4: Implement Improvement Programs		
4A: Identify… **4B**: Develop or adapt… **4C**: Implement… …quality improvement strategies, programs, program components, or tools	-Literature reviews -Development of QI toolkits -Experiments or quasi experi-ments to evaluate QI interventions -Development or adaptation of educational materials or decision support tools (See descriptions	-Pilot test strategies to identify and care for patients with diabetes who have at-risk feet -Multi-site evaluation of scheduling strategies to improve optimal timing of diabetes retinopathy follow-up and therapy -Trial of clinical reminders to improve HIV patient outcomes and

	below for QUERI Implementation Activity Phases: -Single site pilots -Small-scale multi-site evaluations -Region-wide demonstrations -National rollouts)	guideline concordance
Step 5/6: Evaluate Improvement Programs		
Assess improvement program… **5**: …feasibility, implementation, and impacts on patient, family, and system outcomes **6**: …impacts on health-related quality of life (HRQOL)	-Experiments or quasi-experiments to evaluate QI interventions -Development of QI toolkits -Cost analyses (See descriptions below for QUERI Implementation Activity Phases: -Single site pilots -Small-scale multi-site evaluations -Region-wide demonstrations -National rollouts)	-Evaluation of a foot care interven-tion for diabetic patients with diabetes -Eye care intervention trial to study improvements in diabetic patient and system out-comes --Evaluation of eye and foot care interventions for reducing blindness, amputation, and improvements in HRQOL

Appropriate Levels of Intervention

Part of the design of an intervention to implement best practices and its evaluation must include a careful analysis of the appropriate level of the intervention. The unit – and level of analysis in the accompanying evaluation – must conform to the nature of the intervention and its level. For example, if an intervention is conducted at the organizational level, such as the clinic, then the most appropriate unit of analysis is the clinic. However, it may be feasible to analyze data at the individual patient level as well. In order to make appropriate statistical inferences using frequently used approaches (e.g., regression analysis) the hierarchical nature of the data—the fact that patients are nested within clinics, which may be nested within facilities, which may be nested within VISNs—must be taken into account.

Whether an implementation investigator has the ability to randomize subjects to intervention arms in a trial design is a related issue for consideration. Researchers are strongly advised to include a methodologist/statistician who is experienced in the design and conduct of these analyses on the research team.

Typology of QUERI and Non-QUERI Implementation Projects

The following typology provides a method for describing QUERI implementation projects, conducted largely under Steps 4, 5, and 6 of the QUERI process described above. This scheme incorporates the necessary phases to assure adequate development, refinement, evaluation, and assessment of innovative evidence-based implementation programs and strategies. It maximizes the likelihood of successful identification and implementation of beneficial programs to diffuse clinical findings and minimize failed large-scale implementation efforts and, thus, the ineffective use of resources. In addition, use of these labels fosters a consistent understanding and communication among QUERI stakeholders (including QUERI Coordinating Center leaders, investigators, reviewers, HSR&D/Central Office program managers, and VA, as well as non-VA partners).

Single-Site Pilot

A potential improvement program, strategy, or tool that is designed to systematically address quality gaps in provision of evidence-based care should be implemented in a relatively brief study with a fairly short timeline (e.g., 12-18 months) in a single clinic or facility when first proposed, developed, or imported into the VA health care system. This allows initial feasibility testing and refinement or adaptation to the VA environment. These projects:

- Identify incompatibilities between a new program and the underlying structure, operations, and culture;
- Describe important "lessons learned" that permit refinements to the program;

- Produce basic information regarding program acceptance, feasibility, and impacts in a rapid, low-cost manner; and
- Require formative evaluation as part of the initial feasibility testing to permit full delineation of barriers and facilitators and increase the opportunity to export into *small-scale, multi-site evaluation*.

Small-Scale, Multi-Site Evaluation

Activities of this type represent a modest level of investment and commitment, and are designed to produce valid evidence regarding program operations and impacts in a rigorous manner. They are also designed to permit continued refinement of program designs and features. These types of projects:

- Involve 4-8 facilities within 1-2 VISNs,
- May use a modified clinical trial-like design,
- Include a formative evaluation component (to monitor and feed back information, for example, regarding acceptance and impacts),
- Develop and test measurement tools and evaluation methods, and
- Include evaluation of cost and benefits to allow assessment for the feasibility of continuing on to *region-wide demonstration*.

Region-Wide Demonstration

Projects of this type use a larger number of facilities and/or VISNs to prepare for national implementation and incorporation into VHA operations on a regular basis. They should include a sufficient number of sites to permit assessment of feasibility, acceptance, and consistency within regional conditions in order to produce valid evidence of program performance and impacts. Elements include:

- Implementation of an intervention or program in the regular clinical delivery system to reduce quality gaps;
- Measurement of impacts on key patient and caregiver outcomes (clinical, functional status, psychosocial outcomes such as satisfaction and quality of life, etc.);
- Relatively large investment of time and resources;
- Evaluation `of program costs and cost effectiveness; and
- High participation by leadership that is likely to be responsible for national implementation to prepare for "hand-off" to *national rollout*.

National Rollout

These projects represent a type of "post-marketing" phase (using Food and Drug Administration (FDA) terminology), in which an innovative implementation program is deployed system-wide by a VHA operations entity or program. QUERI research teams, Coordinating Centers, or other health

services researchers may provide some support through technical assistance for implementation and evaluation. Hallmarks of these projects include:

- National scope,
- Ongoing monitoring and refinement, and
- Previously demonstrated efficacy, effectiveness, acceptability, relevance, and suitability of program interventions to enhance routine adoption of a targeted evidence-based guideline or recommendation.

Methods for Translating Research Into Practice

While a variety of research methods are used at various stages in the QUERI process, particularly at Steps 4, 5 and 6, quasi-experimental designs may be most appropriate. This is because of inherent difficulties created by having small numbers of sites for study, and limitations in randomizing sites and/or individuals. With careful attention to selecting controls or comparison groups, and in considering threats to validity, quasi-experimental designs can provide the rigor needed to determine whether or not a quality improvement project had positive effects. Additionally, methods in formative and process evaluation become important at these steps, both for improving the intervention itself and to documenting the intervention processes.

Generally speaking, using a variety of broad-based research texts used in the health sciences and in health services research, along with materials on specific methodologies or techniques will offer guidance on research design for projects within the QUERI portfolio. The specific resources (e.g., surveys, focus groups) will be driven by the nature of the proposed project. Examples of such references follow. See also the section in this Guide on formative and process evaluation.

*****This section was contributed by Candy Bowman, PhD, Implementation Research Coordinator for HIV QUERI, and Mary Hogan, PhD, Implementation Research Coordinator for Diabetes Mellitus QUERI.

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Section I Part 4: Formative Evaluation

Research or Evaluation?

The Role of Evaluation in QUERI

In general, there is a lack of agreement about the differentiation or association between research and evaluation. While some define this relationship as evaluation research, others see the two terms as separate concepts with different purposes and techniques. The argument arises from the fundamentally different paradigms that guide these seemingly disparate activities: The research paradigm is one of hypothesis testing, while evaluation is geared toward improving rather than proving.[1]

Paradigmatic differences notwithstanding, a combination of the terms is an accurate reflection of an important type of investigation that is conducted in the Quality Enhancement Research Initiative (QUERI). Within this context, classic research methods provide the means to obtain credible summative information, while standard evaluation modes are used to elicit a better understanding of why interventions succeed or fail. The importance of this understanding becomes more self-evident the closer the research objective is to enabling system-wide change, especially in regard to evidence-based health care delivery.

More specifically, within QUERI, formative evaluation, at times also referred to as process evaluation, is beginning to appear as an important segment of quality improvement research. This type of evaluation is oriented toward understanding the process rather than the outcomes of implementation, as is more typical in research-related efforts. However, formative evaluation is seldom an end in itself; its greatest value lies in the information provided to understand the outcomes of the full study or summative evaluation. Since the concept of formative evaluation may not be familiar to traditional health services researchers, it is the primary focus of this evaluation section – rather than the impact (summative) evaluation.

Terminology

Within the realm of QUERI activities there are two types of evaluation – *formative* and *summative.* Both evaluations are equally important. Summative evaluations generally address the resultant success or effectiveness of a program or intervention and often receive much more attention. However, QUERI project proposals are expected to include plans to complete both types of evaluations. Study designs appropriate to summative evaluation are discussed in Section I, Part 3 of this QUERI Guide, and are more familiar to most health services researchers as designs for intervention studies.

Both definitions and terminology abound for formative evaluation and terms are interchangeable. Definitions abound for formative evaluation, butFor for QUERI purposes these terms are

interchangeable and this type of workthe general intent of formative evaluation is used to describe and monitor the development and progress of an intervention or program. It also provides information with which to adjust the process, as needed, to maximize the effect of the translation strategy. Furthermore, formative evaluation activities can be employed either before or during implementation of the intervention or program.

An example of summative and formative evaluations is seen in a Spinal Cord Injury (SCI) QUERI initiative to improve increase deliveryuse of flu vaccine to veteran patients with SCI and disease by implementing four different interventionsstrategies:

- Patient reminder letters with educational component,
- Provider education,
- Computerized clinical reminders, and
- Nurse standing orders.

Summative evaluations, collected from several sources, examined immunization rates annuallyon an annual basis whether the rates of immunization improved. The formative evaluations examined the process of implementing the four interventionsstrategies. Some of the formative evaluations examined: provider knowledge and attitudes about flu shots, difficulties in using the clinical reminder (and whether adjustments were implemented toand better meet staff needs), variation in provider use of the clinical reminder,difficulties in reaching patients, as well as patient attitudes and knowledge about flu shots.
Information about the process of implementation also may be linked to the summative evaluation that examinesto answer specific questions. For example, the process evaluation may could find that patient contact appears to make the most difference because clinicians never use the computer reminders.

Purposes

Whereas the general purpose of formative evaluation is to assess the process of implementation, specific purposes are numerous. Examples gleaned from the literature include the following goals:

- Assess whether a program or intervention addresses a significant need;
- Modify a proposed program or intervention, as needed;
- Detect unanticipated events systematically;
- Optimize/control implementation to improve potential for success;
- Obtain ongoing input for short-term adjustments;
- Document continual progress;
- Inform future similar implementation efforts, e.g., to other health care sites or to a larger system;

- Avoid "Type III" errors: "Failing to detect differences between the original intervention plan and the ultimate manner of implementation;"[2]
- Understand the extent/dose, consistency, usefulness, context, and quality of an intervention;
- Assist interpretation of program outcomes or worth; and
- Foster an understanding of the causal events leading to change and the specific components of the intervention that most influenced it.

Types

There are in general three distinct types of formative evaluation: Developmental, Implementation-focused, and Progress-focused. All three types may reflect progressive or iterative stages of this general activity within one project.[1]

Developmental formative evaluation is used to enhance the proposed strategy, as needed. Such activities might include:

  - Assessment of factors that are likely to influence the proposed change positively or negatively (e.g., potential barriers and facilitators);
  - Assessment of known prerequisites for the proposed change to occur (e.g., knowledge, attitudes, behaviors, policies); and/or
  - Acquisition of information for selection and refinement/optimization of the strategy (e.g., to remedy or buffer negative factors).

Examples of developmental evaluation include are assessing baseline behaviors, identifying organizational readiness for change and obtaining feedback from a focus group of stakeholders before implementation on the structure of a chosen intervention. , or recognizing change agents within an organization. Some authors include the preparatory literature review as a developmental formative evaluation activity, such as in the identification of potential barriers or the discovery of possible interventions that can facilitate the translation of best practices.
Implementation-Focused formative evaluation identifies "discrepancies between the plan and reality, [and related factors to] keep...the program true to its design or modify it appropriately.".[1] Activities include:

- Monitoring factors that influence the proposed change either positively or negatively; and
- Obtaining information for optimization/refinement of the planned strategy during implementation.

Examples include identifying variable degrees of implementation across sites, determining the degree of adherence to components of the intervention or strategy, and periodically assessing user experiences.

Progress-Focused formative evaluation, the last type, monitors indicators of progress toward the stated project objectives and makes mid-course corrections as appropriate. Examples might be providing feedback to reinforce/motivate users, providing feedback to project staff in order to target potential problem areas, monitoring and reporting intermediate provider behaviors relative to best practices, or measuring intermediate endpoints.

Planning a Formative Evaluation

If a purely developmental formative evaluation is being planned (e.g. to identify determinants of gaps or to generically identify barriers and facilitators) that would be developed as a typical descriptive/observational study. On the other hand, if the formative evaluation is part of an implementation project all three types can be used. Formative evaluations of a full implementation project are the topic of this Section.

As in any evaluation or research endeavor, choices must be made about what to study, and the same is true for the formative evaluation of an intervention project. More than likely, it will not be feasible to assess and evaluate every component of the project, so choices about the most critical aspects must be made. Identifying the aims for the formative evaluation is the first step, . The aims depend on the overall aim of the depending upon the intervention project and its conceptual framework, as well as the planned activities and as well as what is already known about the planned interventions. Then, as in other research endeavors, investigators must:

- Identify the primary questions that derive from the aims,
- Develop instruments and methods to collect data,
- Conduct systematic data collection, and
- Analyze and report data.

The unique character of formative evaluation is that it occurs during the research project, thus the results can be used to describe and inform the process. One use of formative evaluations is to identify parts of the process that need changing refinement so as to maximize the effect of the project. While formative evaluations can be used during the research project, the data may be analyzed in relation to summative findings (outcomes) as well, in order to better interpret findings, particularly in light of a conceptual model. For example – What influenced the degree of success or failure? What was required to "make the change happen?" How did the stakeholders feel about the process? Such information is critical to the expected roll-out of VA implementation projects to the broader system.

The goal of the SCI QUERI Vaccine Initiative project was to increase vaccination rates; the project incorporated several intervention components. One intervention was directed at patients; several were aimed at modifying behaviors of practitioners; and several were designed to cause changes in policy and in information technology interactions. Therefore, each intervention required different formative evaluation plans. For example, one formative evaluation was conducted to learn about

any problems being encountered when personnel used computerized clinical reminders for influenza vaccine so that these problems could be corrected. The formative evaluation for an intervention to encourage the use of standing orders for vaccines by nurses consisted of contact with both the hospital policy offices and the staff at the clinics where the patients were seen. For this intervention to improve vaccine rates, the policy had to be in place, it had to be known to the practitioners who saw patients, and it had to be put into practice.

Both qualitative and quantitative methods are commonly used for formative evaluations in translation projects. Qualitative observations of participants, or discussions with participants, may uncover things that are working well and not working well, and whether program elements are implemented as intended. Quantitative data on certain activities may be collected on an ongoing basis and used to determine whether changes are being made. For example, in a project that intends to have its providers use computerized clinical reminders, whether tthe extent to which remindershose reminders are used as prescribed or planned could be tracked to see if change occurs after certain educational activities. References and Internet sources of information are provided at the end of this chapter for those desiring further information on design and planning issues.

Summary of Formative Evaluation Activities

Overall, formative evaluation in all of its forms aims to achieve the following:

- Assess needs;
- Resolve implementation issues;
- Refine proposed interventions;
- Optimize and control implementation;
- Obtain ongoing input for better understanding, "short-term control and correction" (Dehar);
- Document continual progress;
- Inform future efforts;
- Enable understanding of extent/dose, consistency, usefulness, context of translation strategies;
- Assist interpretation of observed change; and
- Foster understanding of implementation, causal events, and specific components that most influence successful implementation.

*****This section was contributed by Mary Hogan, PhD, Implementation Research Coordinator for Diabetes Mellitus QUERI.

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Examples of Health-Related Process or Formative Evaluation

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Web-based resources related to evaluation

Please note that links to these sites are not endorsements of the site, the organization, or content on those sites. They are provided to assist you in identifying potentially useful information, ideas, or additional resources.

US Government Resources

CDC Evaluation Working Group website (http://www.cdc.gov/eval/index.htm) offers information about the work group, a framework for program evaluation, and an extensive resource listing (http://www.cdc.gov/eval/resources.htm).

The **National Science Foundation**'s Directorate for Education and Human Resources, Division of Research, Evaluation and Communication has a web published User-Friendly Handbook for Mixed Method Evaluations (http://www.ehr.nsf.gov/ehr/rec/pubs/nsf97-153/start.htm). While the examples and content are related to education and learning evaluations, the handbook has information related to evaluation that can be applied to other settings. Other features include an example evaluation plan, tips for analyzing qualitative data, and example materials – such as example observation guides, interview guides, and so forth.

The **Bureau of Justice Assistance** is committed to the importance of program evaluation and to developing and enhancing evaluation capabilities at the state and local levels. Evaluation results provide policy makers and program managers with information for future program development and can be used to modify and improve existing programs. The Evaluation Web site (http://www.bja.evaluationwebsite.org) is designed to provide State Administrative Agency staff, criminal justice planners, researchers and evaluators, as well as local practitioners with a variety of resources for evaluating criminal justice programs and has a page with links to a variety of evaluation resources (http://www.bja.evaluationwebsite.org/html/useful_links/index.html).

Other Government Resources

Human Resources Development Canada offers an example of a formative evaluation of a social program (http://www11.hrdc-drhc.gc.ca/pls/edd/FEMTC_brf.shtml). As part of this project they developed an evaluation toolkit (http://www11.hrdc-drhc.gc.ca/pls/edd/toolkit.list). The section on **Quasi Experimental Evaluation** (http://www11.hrdc-drhc.gc.ca/edd-pdf/qeee.pdf) offers guidance on the issues in quasi-experimental designs, which are commonly used, as well as handling threats to validity and may offer some guidance to those who plan these designs.

Non-Government Resources

The **American Evaluation Association** (http://www.eval.org/) is an international professional association of evaluators devoted to the application and exploration of program evaluation, personnel evaluation, technology, and many other forms of evaluation. The site includes Guiding Principles for Evaluators, meetings and events related to evaluation and links to resources for evaluators, including a listing of online texts and books with "how tos" related to evaluation (http://www.eval.org/EvaluationLinks/onlinehbtxt.htm).

RE-AIM (http://www.re-aim.org) is a systematic way for researchers, practitioners, and policy decision-makers to evaluate health behavior interventions. It can be used to estimate the potential impact of interventions on public health. The group is affiliated with Kansas State University, and

the Robert Wood Johnson Foundation has provided funding for the workgroup and for developing the website. RE-AIM stands for: Reach into the target population; Efficacy or effectiveness; Adoption by target settings or institutions; Implementation—consistency of delivery of intervention; Maintenance of intervention effects in individuals and populations over time.

Resources for Methods in Evaluation and Social Research (http://gsociology.icaap.org/methods/) is a website supported by ICAAP (The International Consortium for the Advancement of Academic Publication) and lists free resources for methods in evaluation and social research. The focus is on "how-to" do evaluation research and the methods used: surveys, focus groups, sampling, interviews, and other methods. Most of these links are to resources that can be read over the web. A few, like the GAO books, are for books that can be sent away for, for free (if you live in the US), as well as read over the web.

The **Action Evaluation Research Institute** (http://www.aepro.org/) is a site with information on action research and evaluation.

Formative Evaluation Research Associates (FERA) (http://www.feraonline.com/) is an evaluation group that has 25 years experience with non-profit organizations. The site includes general information on formative evaluation as well as links to other resources.

The **Skillman Foundation**'s website has an evaluation guide (http://www.skillman.org/pdfs/Evaluation.pdf) that is directed at their grantees or those applying, but which also provides a good overview on evaluation.

The **WK Kellogg Foundation** has several guides that relate to evaluation, and evaluation guide (http://www.wkkf.org/Pubs/Tools/Evaluation/Pub770.pdf), and a guide to the use of logic models to guide program implementation as well as the ensuing evaluation (http://www.wkkf.org/Pubs/Tools/Evaluation/Pub3669.pdf).